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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,059

02/17/2004

Spyridon Artavanis-Tsakonas

7326-132

8386

20583

7590

05/29/2007

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EXAMINER

STOICA, ELLY GERALD

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

05/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,059	ARTAVANIS-TSAKONAS ET AL.	
	Examiner	Art Unit	
	Elly-Gerald Stoica	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*; 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-92 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4-58,68-85 and 89-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 59-67,86 and 88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/17/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III in the reply filed on 04/19/2007 is acknowledged. The traversal is on the grounds that claim 88 (in part) should be included in group III and also in group IV. The arguments of the Applicant were found persuasive and, accordingly, claim 88 (in part) is part of Groups III and IV.

The requirement is still deemed proper and is therefore made FINAL.

Status of the claims

2. Claims 1, 2, and 4-92 are pending. Claims 1, 2, 4-58, 68-85, 87, 89-92 are withdrawn as non-elected claims. Claims 59-67, 86 (in part) and 88 (in part) drawn to method of identification of a Notch modulator by detecting cleavage products are being examined.

Claim objections

3. Claims 86 and 88 are objected to as encompassing non-elected subject matter. Appropriate correction is required.

Priority

4. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent

application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/899, 232, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Claim 86 contains subject matter that was not disclosed in the Application No. 08/899, 232. The subject matter was disclosed in a later-filed application, No. 09/121457 and therefore the priority date for this particular subject matter is the filing date of 07/23/1998.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 59-67, 86 and 88 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubin et al. (U.S. Pat. 5,935,792, 08/10/1999).

Rubin et al. teach that the primary NOTCH translation product is proteolytically cleaved by native KUZ proteins (metalloproteases) as part of the normal biosynthesis of a functional NOTCH receptor (col. 2, lines 5-12), that is, KUZ activates Notch. KUZ-

specific activity or function may be determined by convenient in vitro, cell-based, or in vivo assays: e.g. in vitro binding assays, cell culture assays. The binding target may be a natural intracellular binding target such as Notch protein (col. 4, lines 7-16 and Fig 1 and 2)). Signal transduction involving Notch may be modulated by a wide variety of inhibitors of KUZ Notch protease activity; therefore, the modulator of Kuz activity is necessarily a modulator of Notch activity as defined in the claims 59-67, 86 and 88. Rubin et al. teach methods for modulating signal transduction involving Notch in a cell, comprising the step of modulating KUZ protease activity, e.g. by contacting the cell with a protease inhibitor. The cell may reside in culture or in situ, i.e. within the natural host. (col. 5, lines 21-24). For KUZ protease assays, 'binding' is generally detected by the generation of KUZ substrate cleavage products, which are Notch cleavage products which possess the structural intrinsic properties of claims 59-63, 86 and 88. The protease activity is quantified by the apparent transfer of a label from the substrate to the nascent smaller cleavage product, where the label may provide for direct detection as radioactivity, luminescence, optical or electron density, etc. or indirect detection such as an epitope tag, which can be detected with antibody conjugates (col. 9. lines 19-47). Agents that modulate the interactions of the KUZ polypeptide with its ligands/natural binding targets can be used to modulate biological processes associated KUZ function, e.g. by contacting a cell comprising a KUZ polypeptide with such an agent. Biological processes mediated by KUZ polypeptides include a wide variety of cellular events which are mediated when a KUZ polypeptide binds a ligand e.g. cell differentiation, cell development and neuronal partitioning. The agents are also used to modulate

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processes effected by KUZ substrates, for example Notch (col. 9, lines 54-64). Also taught is the 110 kD cleavage product obtained when upon cleavage of Notch by KUZ metalloprotease (col.17, 25-42) as in claim 61. Rubin et al. claim a method of screening for an agent which modulates the cleavage of a Notch protein by a KUZ polypeptide, comprising the steps of detecting or measuring the amount of Notch protein cleavage products produced, wherein a difference in the identities or amount of Notch protein cleavage products thus produced relative to the identities or amount of said products in the absence of the candidate agent indicates that the agent modulates the cleavage of Notch protein by the KUZ polypeptide (claim 19).

Therefore, Rubin et al anticipate the method of the invention, as claimed in the instant application.

Conclusion

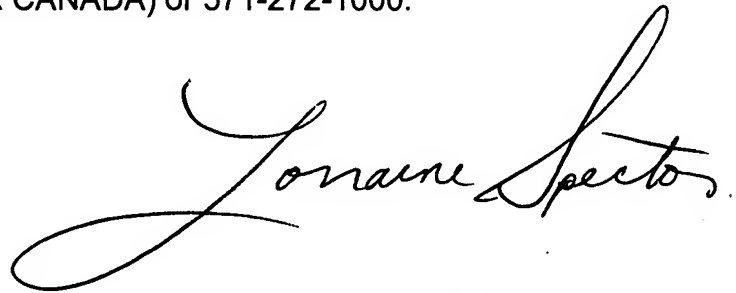
7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, reading "Lorraine Spector". The signature is fluid and cursive, with a large loop at the end of the last name.

**LORRAINE SPECTOR
PRIMARY EXAMINER**